

Dec 18, 2006

PTO/SB/08 (07/05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	09/393,590
				Filing Date	September 9, 1999
				First Named Inventor	Elizabeth Moyer
				Art Unit	1648
				Examiner Name	Sharon L. Hurt
Sheet	1	Of	1	Attorney Docket Number	31242-701.201

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
SA		Response to Solstice Appeal by 01 (S.C.R.A.S.) before European Patent Office Technical Board of Appeal dated October 17, 2006 for EP 1 112 082 B1 (EP Application No. 99 945 649.4)	
SA		Response to Solstice Appeal by 02 (Allergan) before European Patent Office Technical Board of Appeal dated August 2, 2006 for EP 1 112 082 B1 (EP Application No. 99 945 649.4)	

Examiner Signature	Sharon Hurt	Date Considered	2/21/07
--------------------	-------------	-----------------	---------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Feb 2, 2007

PTO/SB/08 (07/05)

Approved for use through 07/31/2006. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	09/393,590
				Filing Date	September 9, 1999
				First Named Inventor	Elizabeth Moyer
				Art Unit	1648
				Examiner Name	Sharon L. Hurt
Sheet	1	Of	1	Attorney Docket Number	31242-701.201

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
Sh		GOODNOUGH, et al. Chapter 12 - Recovery of Type A botulinal toxin following lyophilization. ACS Symposium Series (Formulation and Delivery of Proteins and Peptides). 1994; 567:193-203.	
Sh		SOMMER, et al. Botulinus toxin. J. Infectious Diseases. 1932; 51:243-253.	
Sh		WOOLFORD, et al. Heat inactivation of botulinum toxin Type A in some convenience foods after frozen storage. J. Food Science. 1978; 43:622-624.	

Examiner Signature	Sharon Hurt	Date Considered	2/21/07
-----------------------	-------------	--------------------	---------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

2/20/2007

PTO/SB/08 (07/05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)				<b>Complete if Known</b>		
				Application Number	09/393,590	
				Filing Date	September 9, 1999	
				First Named Inventor	Elizabeth Moyer	
				Art Unit	1648	
				Examiner Name	Sharon L. Hurt	
Sheet	1	Of	1	Attorney Docket Number		31242-701.201

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
Sh		RANSON, Marie, Statutory Declaration dated February 1, 2007 for Australian Patent Application No. 755556 in the name of Solstice Neurosciences, Inc. entitled "Stable liquid formulations of Botulinum Toxin" and in the matter of opposition thereto by Allergan, Inc. (6 pages)	
Sh		Exhibit MR-5 (Schantz et al., Properties and Use of Botulinum Toxin and Other Microbial Neurotoxins in Medicine, Microbiological Reviews, Mar. 1992, p. 80-99) referred to in the Statutory Declaration of Marie Ranson dated February 1, 2007	
Sh		Exhibit MR-6 (Hexsel et al., Letters to the Editor, Dermatol. Surg., May 2004, 30(5):823) referred to in the Statutory Declaration of Marie Ranson dated February 1, 2007	
Sh		RANSON, Marie, further Statutory Declaration dated February 1, 2007 for Australian Patent Application No. 755556 in the name of Solstice Neurosciences, Inc. entitled "Stable liquid formulations of Botulinum Toxin" and in the matter of opposition thereto by Allergan, Inc. (7 pages)	

Examiner Signature	Sharon Hurt	Date Considered	2/21/07
--------------------	-------------	-----------------	---------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number.



Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
(Use as many sheets as necessary)
**Complete if Known**

Application Number	09/393,590
Filing Date	September 9, 1999
First Named Inventor	Elizabeth Moyet
Art Unit	1645
Examiner Name	<del>Sharon Kint</del>
Attorney Docket Number	31242-701.201

Sheet  of **U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US-			

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>4</sup>
		Country Code <sup>3</sup> - Number <sup>2</sup> - Kind Code <sup>2</sup> (if known)				

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>4</sup>
Sh		Unsel, D. W. (1991). Saline. In Medical Dictionary of the English and German Languages (p. 280).	
Sh		Urban & Schwarzenberg. Saline. In Roche Lexikon Medizin dictionary (p. 1400). 1994	
Sh		Walber de Gruyter. Saline. In Psyhyrembel Klinisches Worterbuch dictionary (p. 1483). 1994	
Sh		Decision Revoking the European Patent No. 1112082 dated November 22, 2005 from the European Patent Office	

Examiner Signature	Sharon Kint	Date Considered	9-13-2006
-----------------------	-------------	--------------------	-----------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

2775107.1.DOC

Attorney Docket No. 31242-701.201

Under the paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number.



Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)		<b>Complete if Known</b>		
		Application Number	09/393,590	
		Filing Date	September 9, 1999	
		First Named Inventor	Elizabeth Moyer	
		Art Unit	1645	
Examiner Name				
Sheet		of	Attorney Docket Number	31242-701.201

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US-			

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>4</sup>
		Country Code <sup>3</sup> - Number <sup>2</sup> - Kind Code <sup>2</sup> (if known)				

**NON PATENT LITERATURE DOCUMENTS**

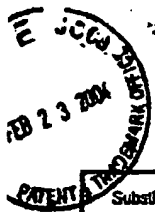
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>7</sup>
SD		Collin, P. H., et al. Saline. In Pons Fachworterbuch Medizin dictionary (p. 368).	
SD		Unsel, D. W. (1991). Saline. In Medical Dictionary of the English and German Languages (p. 280).	
SD		Urban & Schwarzenberg. Saline. In Roche Lexikon Medizin dictionary (p. 1400).	
SD		Walber de Gruyter. Saline. In Psyhyrembel Klinisches Worterbuch dictionary (p. 1483).	
SD		Decision Revoking the European Patent No. 1112082 dated November 22, 2005 from the European Patent Office	

Examiner Signature	SD	Date Considered	Decem - 05
-----------------------	----	--------------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-766-9199) and select option 2.



PTO/SB/018 (08-01)

Substitute for form 1449B/PTO		<b>Complete if Known</b>			
		Application Number	09/393,590		
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Filing Date	September 9, 1999		
		First Named Inventor	Moyer, Elizabeth		
		Art Unit	1645		
		Examiner Name	<del>XXXX</del>		
Sheet	2	of	2	Attorney Docket Number	00211-US-NEW

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 2
SD		M.C. GOODNOUGH, et al. "Stabilization of Botulinum Toxin Type A during Lyophilization," Applied and Environmental Microbiology, 58: 3426-3428 (1992).	
Sh		P. HAMBELTON, et al. "Potency equivalence of botulinum toxin preparations", Journal of the Royal Society of Medicine" 87: 719 (1994)	
Sh		K. MCCLELLAN, et al. "Therapeutic Botulinum Type A Toxin: Factors Affecting Potency," Toxicon, 34(9): 975-85 (1996).	
Sh		E.J. SCHANTZ, et al. "Properties and Use of Botulinum Toxin and Other Microbial Neurotoxins in Medicine," Microbiological Reviews, 56(1): 80-89 (1992).	
Sh		E.J. SCHANTZ, et al. "Preparation and Characterization of Botulinum Toxin Type A for Human Treatment," in "Therapy with Botulinum Toxin," ed. J. Jankovic and M. Hallett, Marcel Dekker Inc. pp. 41-49 (1994).	
Sh		J.P. DOWEIKO, et al. "Role of Albumin in Human Physiology and Pathophysiology," Journal of Parenteral and Enteral Nutrition, 15: 207-211 (1991).	
Sh		B. ASHER "Traitement des rides fronto-orbitaires par injections de toxine botulique, lifting endoscopique, et resurfacing laser," J. Med, Esth et Chir. Derm. XXIII:159-166 (1996) (French language only).	

RECEIVED  
MAR 01 2004

Examiner Signature	SD	Date Considered	May 04
-----------------------	----	--------------------	--------

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.  
\* Applicant's unique citation designation number (optional). \* Applicant is to place a check mark here if English language Translation is attached.